UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

OUTSOURCING FACILITIES ASSOCIATION and NORTH AMERICAN CUSTOM LABORATORIES, LLC d/b/a FARMAKEIO CUSTOM COMPOUNDING, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION and DR. MARTIN A. MAKARY, Defendants, and ELI LILLY AND COMPANY, Intervenor-Defendant.	Case No. 4:24-cv-953-P

ELI LILLY AND COMPANY'S BRIEF IN SUPPORT
OF ITS MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

INTRODUCTION

Just a few weeks ago, this Court concluded that Plaintiffs Outsourcing Facilities Association and FarmaKeio Custom Compounding are unlikely to succeed on the merits of their challenges to the Food and Drug Administration's well-reasoned decision to remove Eli Lilly and Company's tirzepatide medications from the statutory drug-shortage list. That preliminary analysis of Plaintiffs' case has only gotten better with the benefit of the full record. Indeed, while Plaintiffs' most recent filing in this Court—an attempt to secure an injunction pending appeal, filed not long after Plaintiffs voluntarily moved to slow down their preliminary injunction appeal (and asked this Court to enter judgment against them)—dressed up their claims in slightly different garb, none of their new arguments moves the needle. Nor could they. The administrative record confirms what this Court already correctly predicted: Plaintiffs' claims have no basis in law or fact. This Court should grant summary judgment to Defendants.

As Lilly detailed in its preliminary injunction brief, Lilly spent nearly ten years and billions of dollars working to develop and then secure FDA approval for Mounjaro® and Zepbound®, two groundbreaking medicines containing tirzepatide, a macromolecule Lilly discovered. Both medicines meet critical patient needs: Mounjaro® treats type 2 diabetes, and Zepbound® treats chronic weight management and sleep apnea in certain adults. Both medicines faced unprecedented immediate demand for periods after they became commercially available. That immediate demand surge led FDA to place both medicines on its "drug shortage" list—which, in turn, led a cast of so-called "compounders" to begin mass-manufacturing untested, unapproved versions of Lilly's medicines. But, fortunately, the tirzepatide shortage is now over. Owing to its historic, $23 billion manufacturing investment over the past four years, Lilly has been able to meet demand for Mounjaro® and Zepbound® and will be able to do so going forward. FDA accordingly determined that any shortage ended in October 2024 and, after giving Plaintiffs and others another

chance to try to prove that conclusion wrong, reaffirmed that decision in a thorough opinion released December 19, 2024.

As they did at the preliminary injunction stage, Plaintiffs attack FDA's renewed decision under the Administrative Procedure Act. Their arguments are no better now than they were before.

First, as this Court correctly concluded at the preliminary injunction stage, Plaintiffs' procedural APA claims present "a 'lose-lose scenario' for Plaintiffs." ECF No. 101, at 11. The only way a court could logically conclude that FDA's decision to take a drug *off* the shortage list required full-blown notice-and-comment procedures is if the antecedent decision to place a drug *on* the list also required notice and comment. But FDA did not go through notice and comment when it added Lilly's tirzepatide products to the list. Indeed, it has never done so for any drug, either when putting it on the shortage list or taking it off. That is not surprising: As this Court recognized, notice and comment is neither sensible nor appropriate in this context given the time it takes to conduct such proceedings. In all events, even if FDA should have used more formal proceedings, the result would be the same, as Plaintiffs received ample notice and opportunity to persuade FDA that a shortage persists. They failed to do so not because of any procedural infirmities, but because the record makes clear that the shortage has ended.

Second, FDA's decision was neither arbitrary nor capricious. Plaintiffs' *ipse dixit* notwithstanding, FDA "plainly" laid out the parameters of its decision, thoroughly considered the submissions it received, and explained at length what it found probative (or not) and why. ECF No. 101, at 18. As this Court recognized at the preliminary injunction stage, FDA made quite clear what time period it considered in making its determination—and it was not required (nor would it have made sense) to use Plaintiffs' preferred parameters. Nothing in the administrative record undermines the conclusion that FDA's analysis of and reliance on Lilly's comprehensive data

(among other evidence) was both reasonable and reasonably explained. Lilly provided a wealth of data showing that it consistently has fulfilled all wholesalers' orders. FDA investigated that data and confirmed that Lilly's supply meets demand. And while Plaintiffs and their compatriots submitted reams of (largely duplicative) documents indicating that some patients at some points in some places had some trouble acquiring particular doses on demand, the more comprehensive data in the record confirms that those instances were temporary and isolated—and, in all events, not indicative of a shortage nationwide, which is what the statute requires. FDA also reasonably explained why the limited production data supplied by 503B outsourcing facilities and 503A pharmacies did not support finding a shortage. In short, FDA explained why Lilly's supply and demand data confirmed that Lilly's medicines are no longer in shortage and why Plaintiffs' efforts to poke holes in that data do not undermine that conclusion. The APA requires nothing more. Indeed, had FDA reached the opposite conclusion on this record, *that* would have been arbitrary and capricious.

Finally, FDA's long-standing interpretation of the FDCA as focused on whether demand is outpacing supply nationwide accords with text, context, and common sense, whereas Plaintiffs' proposed interpretation defies the plain text, is divorced from the objectives of the statute, and would produce an unworkable system and absurd results.

The Court should grant summary judgment for Defendants on all counts.

BACKGROUND

I. Factual Background

A. The FDCA's Drug Approval Regime.

Prescription medicines require FDA approval, *see* 21 U.S.C. § 355(a), which is famously hard to earn. Medicines that secure FDA approval represent only a fraction of a fraction of the therapies developed and put into preclinical testing. Across the board, a mere 0.02% of potential

treatments that go into preclinical testing end up receiving FDA approval for therapeutic use—and only one in three of that tiny subset will ever recoup its development costs.[1]

"On average, it takes 10-15 years and costs $2.6 billion to develop one new medicine."[2] Each drug must be evaluated through three increasingly complex phases of studies, typically culminating in double-blind, multi-center, placebo-controlled clinical trials. The sponsor must detail every ingredient and component in its FDA application. 21 U.S.C. § 355(b)(1)(A)(i)-(viii). FDA conducts manufacturing inspections to ensure compliance with current good manufacturing practice, reviews the drug's labeling to ensure appropriate disclosure of side effects, warnings, and contraindications, *id.* § 352(f)(1)-(2), and monitors advertising and promotion to ensure it is not misleading. *Id.* §§ 321(n), 352(a)(1), 352(n). FDA also requires manufacturers to track and trace each finished product, to promptly report all adverse events, and to conduct further post-approval studies. Simply put, FDA approval is "the gold standard for safety and effectiveness." Pub. L. 106-387, § 745(b)(5), 114 Stat. 1549, 1549A-36 (2000).

Because obtaining FDA approval is so hard, Congress has incentivized costly investment in breakthrough medicines by granting statutory exclusivities (distinct from intellectual property rights) that allow innovators to be, for a time, the only lawful source of a new medicine. Relevant here, new chemical entity exclusivity is earned whenever FDA approves a new medicine for the first time. 21 U.S.C. § 355(c)(3)(E)(ii), (j)(5)(F)(ii).

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[1] *See* Sandra Kraljevic et. al., *Accelerating Drug Discovery*, 5 Eur. Molecular Biology Org. Reps., no. 9, 2004, at 837, https://tinyurl.com/525p87tp; John A. Vernon & Joseph H. Golec, *Pharmaceutical Price Regulation: Public Perceptions, Economic Realities, and Empirical Evidence* 7 (2008), https://tinyurl.com/2k3hfyw5.

[2] PhRMA, *Research and Development Policy Framework* (Sept. 2024), https://tinyurl.com/5eecdtm9.

B. Lilly Develops Mounjaro® and Zepbound®.

1. Lilly is a medicine company. Throughout its nearly 150-year existence, Lilly has pioneered countless life-changing discoveries and has developed more than 100 medicines across some of the most challenging diseases. It launched 23 medicines over the past decade, including path-breaking therapies for diabetes, obesity, and Alzheimer's disease. And it has 50 new medicine candidates currently in clinical development or under regulatory review.

Creating life-saving and life-changing medicines requires tremendous investments of time, talent, and money—and those costs have only grown over the years. Every year, Lilly re-invests around 25% of its revenue into research and development of future medical breakthroughs, including almost $11 billion in 2024 alone. For those medicines that FDA approves, Lilly utilizes strict controls for manufacturing them in state-of-the-art facilities, which employ thousands of highly specialized personnel in the United States to ensure that Lilly's medicines meet its (and FDA's) rigorous quality and safety standards. *See supra* p.4. Manufacturing an active pharmaceutical ingredient is a difficult and delicate operation—especially when the active pharmaceutical ingredient is a complex macromolecule. Transforming a raw API into a finished medicine can be equally difficult. To ensure the safety and effectiveness of its products, Lilly follows current Good Manufacturing Practices ("cGMP") across the design, monitoring, and control of its manufacturing processes and facilities, from establishing robust quality management systems to obtaining quality raw materials and detecting and investigating product quality deviations. Each step—from synthesizing the API to formulation, device assembly, and packaging of the final product—requires extensive testing and controls and specialized equipment.

2. Lilly dedicated years and significant human and financial capital to research, develop, and bring to market Mounjaro® and Zepbound®. Those efforts eventually paid off: FDA approved Mounjaro® and Zepbound® in 2022 and 2023, respectively, pursuant to Lilly's marketing

applications. Today, each comes in six distinct dosage strengths, with patients typically starting at the lowest strength (2.5mg) and titrating up to higher strengths (up to 15mg) over time, as needed and directed by their doctor.

Mounjaro® and Zepbound® have been commercially available in the United States since they launched. *See, e.g.*, Lilly App.[3] 19, 25 (finding that Lilly f[redacted]). But both medicines immediately generated significant demand, reflecting their value to patients and importance to healthcare providers. The Federal Food Drug and Cosmetic Act requires FDA to "maintain an up-to-date list of drugs that are determined … to be in shortage in the United States," 21 U.S.C. § 356e(a), which FDA defines as "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug," 21 C.F.R. § 314.81(b)(3)(iii)(d)(1), (f); *see also* 21 U.S.C. § 356c(h)(2). *See* Lilly App. 2 (employing that interpretation). After Lilly shared data with FDA showing that supply of its drugs was temporarily outpaced by rapid and overwhelming demand, FDA placed Mounjaro®, and later Zepbound®, on the statutory drug-shortage list in December 2022 and April 2024, respectively.

3. Lilly took swift action to address the high demand for its medicines. It invested even more heavily in its manufacturing capacity, leading to a total commitment of more than $23 billion since 2020 (with another $27 billion recently announced)—the most significant in Lilly's nearly 150-year history—to build, expand, acquire, or obtain internal and external manufacturing facilities in the United States and Europe. Lilly also obtained supplemental FDA approval authorizing the sale of Zepbound® in single-use vials (it originally was approved in auto-injector devices), providing additional supply capacity and access to patients who need Lilly's medicines.

[3] Citations to "Lilly App." are to the separate appendix Lilly filed with this brief.

As a result of Lilly's unprecedented efforts, FDA updated its drug-shortage database in August 2024 to reflect that "[a]ll doses of Mounjaro and Zepbound [were] available."[4] Lilly also shared information with FDA about (among other things) [redacted]. Lilly App. 62-68 (FDA_000307-000313). Two months later, on October 2, 2024, FDA determined that the tirzepatide shortage was resolved, explaining that it had "confirmed with [Lilly] that [its] stated product availability and manufacturing capacity can meet the present and projected national demand."[5]

C. Compounders Take Advantage of FDA's Shortage Determination.

1. "Compounding" means combining or mixing ingredients together to create a medication. While compounding was common in the colonial era, it faded in the nineteenth century, as pharmaceutical companies (including Lilly, founded in Indianapolis in 1876) began producing medicines at scale. Today, the FDCA permits compounding in only narrow circumstances.

Licensed pharmacists and physicians (aka "503As") are permitted to compound one-off versions of drugs in response to a prescription identifying a patient-specific need. *See* 21 U.S.C. § 353a. (For instance, children unable to swallow pills might need liquid "forms of medications for easier consumption." *Pros. & Patients for Customized Care v. Shalala*, 56 F.3d 592, 593 (5th Cir. 1995).) But this limited permission is not an excuse to engage in batch manufacturing or otherwise mass-produce unregulated drugs. Indeed, Congress imposed a series of requirements to ensure that 503As are "engaged in traditional compounding rather than disguised manufacturing." *Med. Ctr. Pharm. v. Mukasey*, 536 F.3d 383, 391 (5th Cir. 2008). One such restriction is that 503As may not "compound regularly or in inordinate amounts … any drug products that are

[4] Ned Pagliarulo, *Zepbound, Mounjaro back in supply as Lilly resolves shortage*, BIOPHARMA DIVE (Aug. 5, 2024), https://www.biopharmadive.com/news/eli-lilly-tirzepatide-supply-fda-doses-shortage/723269/.

[5] *Id.*

essentially copies of a commercially available drug product." 21 U.S.C. § 353a(b)(1)(D). This limitation is crucial to patient safety because 503As compound drugs without registering with FDA, complying with cGMP, or following ordinary drug-labeling rules. *See id.* § 353a(a).

Congress has separately authorized compounding by "outsourcing facilities," which are compounders who have voluntarily registered with FDA. *See id.* § 353b(a)(1), (b)(1)(A). As the name implies, outsourcing facilities are intended to consolidate pharmacy operations that would otherwise occur at individual healthcare facilities. Consolidating pharmacy operations improves public health because, unlike pharmacies, outsourcing facilities must comply with cGMP and report adverse events to FDA. But because drugs compounded by outsourcing facilities (like all drugs made by compounders) are neither approved (or reviewed) by FDA nor required to comply with many other drug-safety requirements, Congress requires outsourcing facilities to comply with "eleven statutory criteria" designed to ensure that they do not become large-scale drug manufacturers. *Athenex Inc. v. Azar*, 397 F. Supp. 3d 56, 59 (D.D.C. 2019). Relevant here, outsourcing facilities usually may not compound any drug that is "essentially a copy of one or more approved drugs." 21 U.S.C. § 353b(a)(5). But when FDA places a drug "on the drug shortage list," registered "outsourcing facilities" may use that drug substance in their compounding operations. *Id.* § 353b(a)(2)(A)(ii). Crucially, however, that limited permission lasts only so long as the drug remains on the shortage list "at the time of compounding, distribution, and dispensing." *Id.* § 353b(d)(2)(A).

The tight restrictions Congress has placed on compounding are the product of a lesson it has learned (repeatedly) over time: Compounding drugs that lack FDA approval or oversight can pose serious risks to patients. For example, in 1990, four patients died after contracting bacterial infections from a compounded cardioplegia solution, and two patients lost an eye and 10 more

were hospitalized after contracting bacterial infections from compounded eye drops.[6] While all of that spurred Congress to impose stricter restrictions on compounding in 1997, compounding nevertheless continued to proliferate—and harm patients. Between 2004 and 2006, 80 patients around the country were infected with bacteria from compounded heparin. And in 2007, three patients were killed by compounded colchicine injections, and eight patients in North Carolina were infected with bacteria (and one killed) by compounded fentanyl.[7]

Congress acted to tighten restrictions once again in 2013 after an entity called the New England Compounding Center shipped 17,000 knockoffs of Depo-Medrol® injection contaminated with fungal meningitis to 23 states, leaving scores dead and hundreds sickened. *See United States v. Cadden*, 965 F.3d 1, 8 (1st Cir. 2020). Even so, unapproved compounded drugs have continued to cause serious harm. For instance, in 2013, 15 patients were infected with bacteria from compounded calcium gluconate injections. In 2016, three children were hospitalized when they received compounded morphine injections that were 2,500 percent superpotent. In 2017, at least 43 patients experienced vision loss, macular swelling, and/or retinal degeneration from compounded intravitreal injections.[8] In 2021, a different compounding pharmacist pled guilty to providing to cataract-surgery patients adulterated compounded drugs that contained "an excessive amount of an inactive ingredient" that can damage sensitive eye tissue[9]; at least 68 patients were injected with the adulterated compounds, at two different surgery centers, over a period of months,

[6] Institute for Safe Medication Practices, *Sterile Compounding Tragedy is a Symptom of a Broken System on Many Levels* (Oct. 18, 2012), https://tinyurl.com/34d7c6cs.

[7] Pew Charitable Trusts, *U.S. Illnesses and Deaths Associated With Compounded or Repackaged Medications, 2001-19* (Mar. 2, 2020), https://tinyurl.com/4rswtudf.

[8] *Id.*

[9] U.S. Food & Drug Admin. & U.S. Dep't of Justice, *Texas Pharmacist Pleads Guilty to Adulterating Drug Used in Cataract Surgeries* (Oct. 13, 2021), https://tinyurl.com/3r2xfkxc.

and patients suffered near-immediate adverse events, including permanent blindness.[10] And many more harmful incidents likely remain unknown—because pharmacies do not have to report them and outsourcing facilities often fail to do so.

2. In response to FDA's shortage determination, many entities saw an opportunity to make quick profits by mass-producing untested and potentially unsafe compounded versions of tirzepatide. Compounded tirzepatide products thus proliferated while Mounjaro® and Zepbound® were on the drug-shortage list—and so did the risks of those knockoff drugs. In July 2024, FDA sent a letter to compounding advocacy organizations highlighting "reports describing patients who experienced adverse events following the administration of compounded … tirzepatide."[11] FDA reiterated that "compounded drug products, including compounded … tirzepatide products, are not FDA-approved" and "do not undergo premarket review by FDA for safety, effectiveness, or quality."[12] On November 1, 2024, FDA issued a warning about drugs compounded by Fullerton Wellness LLC of California after a patient noticed a black particulate in a vial of compounded semaglutide, and a joint FDA-California investigation uncovered conditions at Fullerton that could cause its drugs, including tirzepatide, to become contaminated.[13] And FDA later advised the public of "multiple reports of adverse events, some requiring hospitalization, that may be related to dosing errors" associated with compounded GLP-1 drugs.[14]

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[10] Charlotte Huffman & Mark Smith, *Dozens say they lost eyesight after routine surgery using compounded pharmacy drugs*, WFAA (Feb. 9, 2019), https://tinyurl.com/fwcd2chk (last updated Feb. 13, 2019).

[11] Letter from Shannon Glueck, Pharm.D., U.S. Food & Drug Admin., to Philip Dickison, PhD, RN, Nat'l Council of State Bds. of Nursing (July 16, 2024), https://tinyurl.com/4v9fc4ym.

[12] *Id.*

[13] U.S. Food & Drug Admin., *FDA warns patients and health care professionals not to use compounded drugs from Fullerton Wellness* (Nov. 1, 2024), https://tinyurl.com/56mb4u9u.

[14] U.S. Food & Drug Admin., *FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss* (Mar. 17, 2025), https://tinyurl.com/483u6td6.

Leading organizations, state governments, and foreign governments have also expressed concern. Thirty-eight state and territory Attorneys General and State Drug Task Forces have warned the public about the dangers of these unsafe and unapproved products, including compounders using "non-sterile ingredients" and taking "no steps to sterilize them."[15] The Obesity Society, Obesity Action Coalition, and Obesity Medicine Association issued a joint statement regarding compounded GLP-1 medications, stating, "[u]nfortunately, many of the available alternatives [to GLP-1 therapies], like compounded versions of semaglutide and tirzepatide, are not what they are advertised to be."[16] The Pediatric Endocrine Society has advised that "[c]linicians and patients [] should exercise caution when exploring options for non-brand name medications, particularly avoiding the use of non-FDA approved medications and those that come from non-FDA-approved compounding pharmacies."[17] And the JAMA Health Forum published a study that most websites selling compounded anti-obesity medications exclude important safety information and mislead consumers about the safety and effectiveness of their products.[18] Other patient and consumer groups have issued similar warnings, including the National Consumers League and the American Diabetes Association, which recommended that patients avoid compounded products "due to uncertainty about their content, safety, quality, and effectiveness."[19]

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[15] Nat'l Ass'n of Attys' Gen., *State and Territory Attorneys General Urge FDA to Take Action Against Counterfeit and Illegally Sold GLP-1 Drugs*, (Feb. 19, 2025), https://tinyurl.com/ye48f3h8; U.S. Food & Drug Admin., *FDA warns patients and health care professionals not to use compounded drugs from Fullerton Wellness* (Nov. 1, 2024), https://tinyurl.com/56mb4u9u.

[16] Obesity Med. Ass'n, *Leading Obesity Expert Organizations Release Statement to Patients on Compounded GLP-1 Alternatives* (Jan. 8, 2024), https://tinyurl.com/2zaky86a.

[17] Pediatric Endocrine Soc'y, *Statement on use of compounded semaglutide and other GLP-1 receptor agonists* (Jan. 16, 2024), https://tinyurl.com/s3j2y8k4.

[18] Ashwin Chetty, et al., *Online Advertising of Compounded Glucagon-Like Peptide-1 Receptor Agonists*, JAMA HEALTH FORUM (Jan 17, 2025), https://tinyurl.com/4w7vv72a.

[19] Nat'l Consumers League, *NCL urges the public to heed warnings about unregulated versions of GLP-1 weight loss drugs* (Feb. 4, 2025), https://tinyurl.com/mryhxn8j; Am. Diabetes Ass'n, *The American Diabetes Association Announces Statement on Compounded Incretin Products* (Dec. 2, 2024), https://tinyurl.com/rhd5nvjy.

Concerns about unsafe compounded drugs purporting to contain tirzepatide have also garnered international attention. Australia recently banned the development and sale of compounded anti-obesity medications due to "increasing community concern" and "increasing reports of patients coming to harm from" compounded weight loss drugs.[20] The ban—effective October 2024—targets compounded drugs that are "being misrepresented and sold as replica … Mounjaro®."[21] As Mark Butler, Australia's Minister for Health and Aged Care, said, "Australians should be able to have faith in the medications they use, including compounded medicines," and the ban "will protect Australians from harm and save lives."[22] Likewise, the South African government has proposed to prohibit the development of compounded GLP-1s. South Africa's regulatory authority has "noted with concern the number of compounded, substandard, and/or falsified versions" of tirzepatide products being sold to the public since "[t]he complexity of compounding GLP1 agonists, which are sterile medicines containing complex active substances[,] poses a public health and safety risk."[23] "More recently, healthcare regulators in [both] Brazil[] and Ireland have warned patients against using these unapproved knockoffs."[24]

II. Procedural Background

1. Plaintiff FarmaKeio is a large-scale drug manufacturer operating under the guise of Section 503A pharmacy compounding. By its own telling, FarmaKeio sold $1,750,000 to $2,000,000 worth of unapproved, untested tirzepatide *each month* over the past year, ECF No. 65,

[20] Dep't of Health and Aged Care, *Protecting Australians from unsafe compounding of replica weight loss products* (May 22, 2024), https://tinyurl.com/45u9rpe3.

[21] *Id.*

[22] *Id.*

[23] South African Health Prods. Regul. Auth., *SAHPRA's Position on GLP1 and GIP-GLP1 Products That Are Compounded, Substandard And Falsified* (Nov. 8, 2024), https://tinyurl.com/2wyj4za9.

[24] Eli Lilly and Company, *News Release -- Lilly commends ITC ruling cracking down on the unlawful importation and sale of knock-off tirzepatide products that put Americans at risk* (Dec. 23, 2024), https://tinyurl.com/j5fa6vv4.

at 23, and produced [redacted] Lilly App. 236 (DeNeui Decl. ¶ 14). Plaintiff OFA is a trade association that claims to represent outsourcing facilities that likewise routinely compounded tirzepatide while Mounjaro® and Zepbound® were on FDA's shortage list. ECF No. 68, at 3-4 ¶ 5.

Five days after FDA declared that the shortage was over, Plaintiffs filed this lawsuit. *See* ECF No. 1. Plaintiffs sought a temporary restraining order and a preliminary injunction the next day. ECF Nos. 7-8. FDA responded by filing an unopposed motion for voluntary remand and stay, asking the Court to permit it to "reevaluate the decision at issue in this case." *See* ECF No. 27, at 1. This Court granted FDA's motion the same day. ECF No. 28.

2. During the two months that FDA was reevaluating its decision, Lilly provided FDA with a host of detailed, quantitative data, including: [redacted] stock reports [redacted] showing that Lilly maintained [redacted] of finished product and [redacted] of unfinished product in its net inventory from [redacted],[25] Lilly App. 103, 129-30, 138, 230 (FDA_000448, 000474-475, 000483, 000575); historic data on cumulative supply and demand for [redacted] *see, e.g.*, *id.* at 229 (FDA_000574); [redacted], *see id.* at 230 (FDA_000575); and data about [redacted], *id.* at 117-18 (FDA_000462-000463). FDA probed this data, inquiring about Lilly's sources and methodologies, and seeking additional data or responses to claims made by other parties, *see, e.g.*, *id.* at 77-79, 108-11 (FDA_000415-000417, 000453-000456), and Lilly replied with lengthy and

[25] The data also [redacted]. *See, e.g.*, Lilly App. 103 (FDA_000448).

detailed responses, *id.* at 80-90, 114-32, 143-47 (FDA_000422-000432, 000459-000477, 000488-000492).[26]

In stark contrast to Lilly's comprehensive hard data, Plaintiffs and their cohorts offered a collection of form letters, ECF No. 110-4, at 23-24, 30-31, 39-40 (FDA_000828-000829, FDA_000835-000836, FDA_000844-000845), unverified snapshots (many of them undated), *see, e.g.*, ECF Nos. 110-7, at 9 to 110-8, at 31 (FDA_000982-001016), results of internet polls, *e.g.*, ECF No. 110-6, at 6-9 (FDA_000970-000973), and news articles, ECF No. 110-3, at 52-54 (FDA_000757-000759), almost all addressing supply and demand (if at all) only in isolation, at a hyper-localized level, and often just for a single dose, not all 12 that Lilly makes.

3. After thoroughly analyzing all the submissions it received, FDA issued a declaratory order and 32-page supporting memorandum on December 19, 2024, confirming that Lilly's tirzepatide medicines are not in shortage. *See* ECF No. 32, at 1; Lilly App. 1. The order "revoke[d] and replace[d]" FDA's earlier October 2 determination but came to the same conclusion: "[T]he tirzepatide injection product shortage is resolved." Lilly App. 1.

In reaching that conclusion, FDA explained, it considered "detailed information" Lilly provided "regarding its production and inventory of [Mounjaro® and Zepbound®] at various points in time, including stock reports that show quantities supplied and demanded, and inventory held in stock, for all strengths of [Mounjaro® and Zepbound®]; cumulative quantities supplied to and demanded by its customers [redacted]; projected demand and supply in future months; and wholesaler inventory data, among other information." Lilly App. 2.

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[26] Lilly explained [redacted]. For example, [redacted]. Lilly App. 120 (FDA_000465). Lilly re[redacted] such that [redacted]. *Id.*

First, FDA explained that the stock reports "demonstrate that" Lilly has been "fulfill[ing] all existing orders" from wholesalers "while generally maintaining … excess inventory." *Id.* at 17. In particular, those reports showed that, by the time FDA was reconsidering the delisting decision, Lilly was [redacted]. *See, e.g.*, *id.* at 103, 129-30, 138, 230 (FDA_000448, 000474-000475, 000483, 000575). And while FDA acknowledged that [redacted] the agency found that the data [redacted] supplementing the inventory with quantities [redacted] *Id.* at 17; *see also id.* at 120 (FDA_000465) (email from Lilly to FDA explaining that, [redacted]). As a result, inventory data showed wholesalers [redacted] which FDA noted [redacted] *Id.* at 24. Indeed, distributors had [redacted] in the [redacted] *Id.* at 23-24 (citing *id.* at 117-18 (FDA_000462-000463)).

FDA also concluded that Lilly's supply-and-demand data confirmed that t[redacted] *Id.* at 19-22, 27. Based on data from [redacted]

[redacted] *Id.* at 22, tbl. 4; *see id.* at 229 (FDA_000574). And those numbers [redacted] *SeeId.* at 22, tbl. 4.

Finally, FDA found that Lilly's [redacted]. *Id.* at 27 (citing *id.* at 229 (FDA_000574)). Lilly modeled its projections using [redacted]. *Id.* at 86, 89 (FDA_000428, 000431). And while Lilly acknowledged that no one can [redacted] it explained why [redacted] *Id.* at 126 (FDA_000471). FDA found Lilly's model [redacted]. *Id.* at 26.

FDA gave the same careful treatment to the voluminous evidence submitted by Plaintiffs and other stakeholders trying to demonstrate that a shortage persisted. After methodically reviewing all these submissions and the information contained in them, FDA detailed why they suffered from "important limitations" and did "not demonstrate that Lilly will be unable to meet projected demand, especially when weighed against the Lilly-provided data." *Id.* at 14.

In short, the additional post-October data confirmed that FDA's initial assessment was correct: Mounjaro® and Zepbound® are no longer in shortage. Nevertheless, "to avoid

unnecessary disruption to patient treatment and to help facilitate an orderly transition," FDA announced that it would exercise its discretion to withhold enforcement against unlawful tirzepatide compounding for 60 days as to 503A compounders and 90 days as to 503B facilities. *Id.* at 9, 12. At the same time, FDA acknowledged that its enforcement-discretion period was "relatively brief" but longer than guidance suggested, balancing "concerns about potential effects on patients" and the interest in "protect[ing] patients from unnecessary exposure to drugs that have not been shown to be safe and effective, and that offer fewer assurances of manufacturing quality." *Id.* at 42-43.

4. FDA advised the Court of its declaratory order on the same day it was published. Shortly thereafter, Lilly filed a motion to intervene as a defendant, which the Court granted on January 6, 2025. ECF Nos. 34-35, 51. Meanwhile, Plaintiffs and FDA jointly moved to reopen the litigation. ECF No. 38.

Plaintiffs then filed an amended complaint. While the amended complaint added facts and arguments based on developments since the filing of the original complaint, Plaintiffs' claims remained substantively the same. Specifically, Plaintiffs claim (in Counts One and Six) that FDA violated the APA procedurally by not engaging in notice and comment and not publishing its delisting decision in the Federal Register. ECF No. 68, at 17-19, 23-24. Next, they claim (in Counts Two, Three, and Four) that FDA's delisting decision was arbitrary and capricious because it did not identify key parameters and was "facially incoherent and inconsistent" in construing Lilly's data and improperly discounting evidence of ongoing shortage. *Id.* at 31-34. Finally, Plaintiffs claim (in Count Five) that FDA's interpretation of what constitutes a "shortage" under the FDCA is "overly restrictive" and unlawful. *Id.* at 34-35.

5. Plaintiffs sought a preliminary injunction based solely on their APA claims, ECF No. 66, at 7-23; *see* ECF No. 101, at 6, which this Court denied. ECF No. 101.

The Court started with Plaintiffs' procedural arguments. Because only substantive rules require formal notice-and-comment procedures, the Court began its analysis by "determin[ing] how to categorize the Delisting Action." *Id.* at 6-7. The Court had no trouble concluding that the delisting decision was an informal adjudication, not a rulemaking. The decision "undoubtably has immediate legal consequences for specific parties," *id.* at 15: Once Lilly's drugs were removed from the shortage list, outsourcing facilities could no longer use tirzepatide in their compounding operations. *See* 21 U.S.C. § 353b(a)(2)(A)(ii), (d)(2)(A). And rather than "promulgate a new policy-type rule or standard that will govern the FDA's future actions," the decision to remove the medicines from the shortage list was "a specific factual determination based on the statutory definition of shortage." *Id.* at 15. The Court therefore concluded that the decision was an informal adjudication, and that FDA acted within its discretion in charting that course and eschewing formal notice-and-comment procedures and publication in the Federal Register. *Id.* at 7-8, 16. Indeed, the Court suggested that it would have been an abuse of discretion for the agency to subject its delisting decision to all the formal trappings of notice-and-comment rulemaking, as "notice-and-comment rulemaking is incompatible with Congress's mandate to keep an up-to-date list." *Id.* at 8-9.

Turning to Plaintiffs' substantive challenges, the Court held that FDA's delisting decision was not arbitrary and capricious. *Id.* at 17-28. "Plaintiffs first argue[d] that the Delisting Action is arbitrary and capricious because it fails to identify what time period the FDA looked at to make its shortage determination." *Id.* at 18. The Court rejected that argument because FDA "explicitly provide[d]," "[o]n multiple occasions," "what period of time on which it based its shortage

determination." *Id.* The Court next rejected Plaintiffs' argument that "the Delisting Action is facially incoherent and inconsistent." *Id.* at 19. As the Court explained, "[t]he question before the FDA was" whether "'the demand or projected demand for the [Lilly] drug[s] within the United States exceed the supply of the [Lilly] drug[s].'" *Id.* at 21 (alterations in original) (quoting 21 U.S.C. § 356c(h)(2)). Because "FDA answered that question in the negative and therefore found that the shortage had ended," "the question before the Court [was] whether the FDA's decision, that supply of the Lilly drugs outpaced demand for a period of time, was reasonable in light of the evidence before it." *Id.* The Court "answer[ed] that question in the affirmative," rejecting Plaintiffs' contentions that FDA erred by "consider[ing] cumulative data" for the whole "period of time" at issue, "start[ing] [redacted]" (the beginning of the relevant period), or relying on Lilly's estimated data. *Id.* at 21-24. Finally, the Court rejected Plaintiffs' claim "that the Delisting Action 'arbitrarily waved away all evidence of shortage.'" *Id.* at 24 (quoting ECF No. 65, at 19). FDA did not simply take Lilly's word for it that the shortage had ended; on the contrary, the agency "scrutinized and rejected some of Lilly's evidence based on the same standards it applied to the countervailing evidence." *Id.* Applying those standards, FDA reasonably determined that the countervailing evidence did not undermine the information provided by Lilly or the agency's conclusion that the shortage has ended. *Id.* at 25-28.

Based on these conclusions, the Court held that Plaintiffs are not likely to succeed on the merits of any of their APA claims. *Id.* at 17, 28. The Court found that the equities and public interest did not favor Plaintiffs either, and thus denied their motion. *Id.* at 30.

ARGUMENT

"When assessing a summary judgment motion in an APA case, 'the district judge sits as an appellate tribunal.'" *Permian Basin Petroleum Ass'n v. Dep't of the Interior*, 127 F. Supp. 3d 700, 706 (W.D. Tex. 2015) (quoting *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C.

Cir. 2001)). That is so because, "[u]nder the APA, it is the role of the agency to resolve factual issues to arrive at a decision that is supported by the administrative record." *Hi-Tech Pharmacal Co., Inc. v. FDA*, 587 F. Supp. 2d 13, 18 (D.D.C. 2008). Thus, "the entire case on review is a question of law, and only a question of law," *Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993), and summary judgment "merely serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review," *Oceana, Inc. v. Locke*, 813 F. Supp. 2d 95, 106 (D.D.C. 2011). For that reason, "[t]he summary judgment procedure is particularly appropriate in cases in which the court is asked to review or enforce a decision of a federal administrative agency." *Girling Health Care, Inc. v. Shalala*, 85 F.3d 211, 214-15 (5th Cir. 1996) (citation omitted). Judicial review under the APA is limited to the administrative record, 5 U.S.C. § 706, and "the party challenging an agency's action as arbitrary and capricious bears the burden of proof." *San Luis Obispo Mothers for Peace v. NRC*, 789 F.2d 26, 37 (D.C. Cir. 1986). Because all of Plaintiffs' claims fail as a matter of law, the Court should award summary judgment to Defendants.

I. Plaintiffs' Procedural Claims Fail As A Matter Of Law.

Plaintiffs make two procedural allegations under the APA. First, in Count One, they claim that FDA was required to use formal notice-and-comment procedures before issuing its delisting decision because (they say) that decision is a legislative rule. ECF No. 68, at 17-19. Relying on the same (mistaken) premise, Plaintiffs claim in Count Six that FDA was required to publish its delisting decision in the Federal Register. *Id.* at 23-24. Both claims fail out of the gate because FDA's delisting decision is not a legislative rule. But even if Plaintiffs' premise were correct, their procedural claims would still get them nowhere. It is black-letter law that procedural missteps do not require correction when the complaining parties received all the notice and opportunity to

comment that they would have been afforded under 5 U.S.C. § 553. That is precisely the case here.

A. FDA's delisting decision was an adjudication that did not require formal notice-and-comment procedures or publication in the Federal Register.

1. At the outset, as this Court explained in denying their preliminary injunction motion, "this issue is a 'lose-lose scenario' for Plaintiffs." ECF No. 101, at 11. The APA "mandate[s] that agencies use the same procedures when they amend or repeal a rule as they used to issue the rule in the first instance." *Perez v. Morg. Bankers Ass'n*, 575 U.S. 92, 101 (2015). If Plaintiffs were correct that delisting decisions require formal notice and comment, then listing decisions would as well. ECF No. 101, at 10. But FDA did not utilize notice-and-comment procedures when it decided to place Lilly's medicines on the shortage list. So if Plaintiffs were correct, then FDA's original decision to list Lilly's medicines would be *ultra vires*, and the medicines should be off the list for that reason alone—leaving Plaintiffs with no legal basis for continuing "to compound their versions of the Lilly Drugs." *Id.* at 11. On the flip side, if FDA could properly place Lilly's medicines *on* the list without going through formal notice-and-comment procedures (as Plaintiffs seem to agree it could), then FDA could properly take them *off* the list without notice and comment too. *See id.* at 12 n.4 (rejecting Plaintiffs' argument "that the FDA adding a drug to the shortage list is less legally consequential than removing a drug from the list," and explaining that "the opposite [is] true"). Either way, Plaintiffs lose. *Id.* at 11-12.

That is reason enough to grant summary judgment for Defendants on Count One. Plaintiffs are also wrong on the merits. FDA's delisting decision was not a legislative rule required to go through formal notice and comment. Rulemakings are "proceedings for the purpose of promulgating policy-type rules or standards." *United States v. Fla. E. Coast Ry. Co.*, 410 U.S. 224, 245 (1973). Adjudications, by contrast, are "proceedings designed to adjudicate disputed

facts," *id.*, or to resolve a "concrete and narrow" question of how to apply the law in a way that "would have an immediate and determinable impact on specific factual scenarios," *City of Arlington v. FCC*, 668 F.3d 229, 243 (5th Cir. 2012). That is exactly what happened here. FDA's delisting decision did not interpret the FDCA or "promulgate a new policy-type rule or standard that will govern the FDA's future actions." ECF No. 101, at 15. Nor did it "change or interpret the statutory definition of shortage." *Id.* It simply resolved the fact-specific question of whether a shortage of Lilly's medicines persists, based on whether the supply of Mounjaro® and Zepbound® exceeds the demand nationwide. *Id.* at 15-16 ("[T]he FDA's Delisting Action simply looked at the evidence presented and made a factual determination on whether one number was bigger than another."). That is not a legal interpretation of the statute; it is an adjudication of facts based on the evidence that Lilly, Plaintiffs, and other interested entities presented. *Id.* And "[t]here is no notice and comment requirement for an agency adjudication." *Shell Offshore Inc. v. Babbitt*, 238 F.3d 622, 627 (5th Cir. 2001).

FDA's determination also had an immediate and determinable impact—another hallmark of an adjudication. *See* ECF No. 101, at 13-14. When FDA removed Mounjaro® and Zepbound® from the shortage list, outsourcing facilities could no longer compound tirzepatide, effective immediately. That is not disputed. In fact, Plaintiffs' entire lawsuit is premised on "the immediate effect the Delisting Action has on them": "[T]hey argue that the removal of the Lilly Drugs from the shortage list will force their tirzepatide products 'off the market[.]'" *Id.* at 15 (quoting ECF No. 65 at 2, 23). This case is thus far afield from *Safari Club Int'l v. Zinke*, 878 F.3d 316 (D.C. Cir. 2017), where the Fish and Wildlife Service issued a prospective ban on imports of sport-hunted elephant trophies based on a policy judgment about whether and when killing elephants enhances the species' survival. *Id.* at 333-34. The Service's decision there "did not cancel any

prior but unfulfilled importation approvals"; it "only served to govern the Service's consideration of future applications." ECF No. 101, at 15. As a result, it "had no immediate impact on a specific party." *Id.* The opposite is true here: outsourcing facilities could no longer produce tirzepatide "'upon the issuance of the Delisting Action.'" *Id.* at 16 n.6.

Plaintiffs try to turn that to their advantage, insisting that FDA's decision must be a rulemaking because it "has the force and effect of law." ECF No. 68, at 18 (quoting *Perez*, 575 U.S. at 96). That is a non sequitur. Whether a rule "ha[s] the 'force and effect of law'" is the dividing line between *legislative* rules and *interpretive* rules, only the former of which must go through notice and comment. *Perez*, 575 U.S. at 96; *see also Mock v. Garland*, 75 F.4th 563, 579 (5th Cir. 2023) (explaining that legislative rules "*make substantive law*," and it "is only when the agency seeks to *make substantive law* that notice and comment is required" (quoting *Flight Training Int'l, Inc. v. FAA*, 58 F.4th 234, 241 n.5 (5th Cir. 2023))). It is not the dividing line between rulemaking and adjudication. Indeed, adjudications are *supposed* to "have an immediate and determinable impact." *City of Arlington*, 668 F.3d at 243. They just have that impact by resolving concrete disputes in the context of "specific factual scenarios," *id.*, rather than by making broader pronouncements of law or policy.

Nor does it matter that FDA's delisting decision affects multiple entities. ECF No. 101, at 12-13. While "[a]djudications typically resolve disputes among specific individuals in specific cases, whereas rulemaking affects the rights of broad classes of unspecified individuals," "an agency need not be presented with a specific dispute between two parties" for an action to be an adjudication, "because [5 U.S.C.] § 554 does not limit an agency's use of declaratory rulings to terminating controversies between parties." *City of Arlington*, 668 F.3d at 242-43. It is therefore long settled that "an adjudication can affect a large group of individuals without becoming a

rulemaking." *Goodman v. FCC*, 182 F.3d 987, 994 (D.C. Cir. 1999) (citing *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 292 (1974)). Take, for instance, the NDA approval process. *See* 21 U.S.C. § 355(d)-(g). When FDA approves an NDA for a new active moiety for the first time, that action has the immediate consequence of prohibiting FDA from even accepting a follow-on application for a drug containing the same active moiety from any generic drug manufacturer, and it likewise imposes prohibitions on the compounding of drugs that are essentially copies of the now-approved medicine. *See id.* §§ 353b(a)(5), (d)(2)(A); 355(c)(3)(E)(ii), (j)(5)(F)(ii). Yet FDA's review and consideration of an NDA is self-evidently an adjudication. *Compare id.* § 355(c)(1)(A), (d) (at the end of its review, FDA must issue an "order" either approving or refusing to approve the application), *with* 5 U.S.C. § 551(6) (an "order" is a "final disposition … in a matter other than rule making"). And if there were any doubt, "[t]he Supreme Court has endorsed the FDA's use of informal adjudications to approve NDAs and remove unsafe drugs from the market, despite those adjudications triggering broad sweeping effects on 'several persons or manufacturers.'" ECF No. 101, at 13; *see also id.* at 13 n.5.

In short, FDA's delisting decision was an adjudication, so the APA's notice-and-comment requirements do not apply. *Id.* at 6-16. Plaintiffs' first claim therefore fails as a matter of law.

2. Plaintiffs' sixth count fails as a matter of law for the same reason. Plaintiffs claim that FDA should have published the delisting decision in the Federal Register. ECF No. 68, at 23-24. But 5 U.S.C. § 552(a)(1)(D) requires an agency to publish only "substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency." For all the reasons just discussed, the delisting decision was not a legislative or substantive rule. So FDA did not need to publish the

decision in the Federal Register for the same reason that it did not need to subject it to notice-and-comment procedures. *See* ECF No. 101, at 6.

B. Plaintiffs were not prejudiced by any alleged procedural missteps.

Counts One and Six also fail as a matter of law because Plaintiffs were not prejudiced by any alleged procedural missteps. The APA mandates that "due account shall be taken of the rule of prejudicial error." 5 U.S.C. § 706; *accord Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 591 U.S. 657, 684 (2020); *United States v. Johnson*, 632 F.3d 912, 930 (5th Cir. 2011). The "touchstone" of that analysis "is 'whether it is clear that the lack of notice and comment did not prejudice the petitioner.'" *City of Arlington*, 668 F.3d at 244 (quoting *Johnson*, 632 F.3d at 931). And the burden falls squarely on "the party asserting error to demonstrate prejudice." *Id.* at 243 (quoting *Air Can. v. Dep't of Transp.*, 148 F.3d 1142, 1156 (D.C. Cir. 1998)). Plaintiffs cannot make that showing here. As Plaintiffs admitted in their preliminary injunction briefing, not only were they "aware of FDA's consideration"; they "were able to provide evidence." ECF No. 66, at 12. Indeed, Plaintiffs have not identified a single piece of evidence that they did not submit, but would have submitted, had FDA used formal notice-and-comment rulemaking procedures.

Nor could they, because FDA abided by virtually all the requirements of notice-and-comment rulemaking (even though, again, it did not need to). *Cf. Little Sisters*, 591 U.S. at 683-84 (holding that agencies satisfy the APA when they provide all required elements, "[f]ormal labels aside"). Section 553 of the APA requires an agency engaged in notice-and-comment rulemaking to publish a proposed action in the Federal Register, identify the legal authority for the action, describe the subjects or issues involved, provide an opportunity to submit views, concisely state its final reasoning, and leave 30 days before the rule takes effect. *Id.* at 683-86 (citing 5 U.S.C. § 553(b)). FDA effectively fulfilled all but one of those requirements. FDA's voluntary remand motion identified the legal authority for its delisting decision. ECF No. 27, at 1 (citing 21 U.S.C.

§§ 356e(a)). That motion indicated the subjects or issues involved: delisting of Lilly's tirzepatide products. *See id.* at 1-2. FDA accepted submissions from Plaintiffs and other interested parties regarding whether a shortage persisted. *See, e.g.*, Lilly App. 2 (describing FDA's consideration of "potentially relevant information … from patients, healthcare providers, and others, including compounders"). FDA explained its reasoning in its declaratory order and accompanying decision memorandum. *See id.* at 1-44. Finally, FDA exercised its discretion to not pursue enforcement actions against 503A and 503B compounders for 60 and 90 days, respectively, from the date of the order—a doubling and tripling of the time required by § 553 for a rule to take effect. *Id.* at 4. The only requirement with which FDA did not comply was publishing notice in the Federal Register. But Plaintiffs have acknowledged that they had actual notice—indeed, they not only "were aware of FDA's consideration," but "were able to provide evidence," ECF No. 66, at 12—and that is enough under the APA, *see* 5 U.S.C. § 553(b) (publication not required in cases involving "actual notice").

Plaintiffs are thus left suggesting that maybe someone *else* might have provided more evidence to FDA had all the formal requirements of notice and comment been followed. But Plaintiffs must show harm to "the petitioner" (i.e., themselves), not to some unidentified, other hypothetical commenter. *City of Arlington*, 668 F.3d at 243-44; *see also Little Sisters*, 591 U.S. at 684. At any rate, their claim is hard to take seriously considering that Plaintiffs undertook an extensive "internet letter-writing campaign," Lilly App. 31, to ensure that commenters would flood FDA with evidence and submissions supporting their claim that the shortage persisted—which their allies did in spades. So even assuming *arguendo* that a plaintiff could invoke prejudice suffered by someone else, all Plaintiffs have here is speculation—and especially weak speculation, given the mountain of evidence FDA reviewed.

In short, Plaintiffs received all the benefits of a rulemaking. For that reason, too, their procedural APA claims fail as a matter of law.

II. Plaintiffs' "Arbitrary And Capricious" Claims Fail As A Matter Of Law.

Plaintiffs' substantive APA claims fare no better. "The arbitrary or capricious standard requires that agency action be reasonable and reasonably explained." *Texas v. Biden*, 589 F. Supp. 3d 595, 618 (N.D. Tex. 2022). FDA's delisting decision easily satisfies that standard. After voluntarily reevaluating its initial determination, FDA issued a 32-page memorandum summarizing and addressing the submissions presented to it from all sides. FDA identified the data and information on which it relied and explained how it weighed everything before it, including materials presented by Plaintiffs and similarly situated entities. And FDA prioritized reliable, holistic data about manufacturing supply and orders from distributors for [redacted] over cherry-picked, anecdotal, or unexplained snapshots purporting to show contextless "difficulty" in obtaining Mounjaro® and Zepbound®. That was not only eminently reasonable but in fact the *only* reasonable course FDA could take given how overwhelmingly the record supported the conclusion that Lilly's medicines are no longer in shortage. Plaintiffs' arbitrary-and-capricious claims thus all fail as a matter of law.

A. FDA properly identified key parameters.

Plaintiffs' first arbitrary-and-capricious claim argues that FDA failed to indicate what period of time it considered in making its shortage determination. As this Court already recognized in denying Plaintiffs' preliminary injunction motion, this argument "plainly fails." ECF No. 101, at 18. FDA's decision memorandum explained in numerous places that the agency considered (1) supply and demand data for Lilly's medicines from [redacted], (2) the [redacted], and (3) projections for supply and demand [redacted]

[redacted]. *See* Lilly App. 13, 19-22, 26-27. Simply put, "FDA sufficiently identified what time period it considered in making the shortage determination." ECF No. 101, at 18.

Unable to seriously dispute that FDA did so, Plaintiffs alternatively fault FDA for failing to "provide any comparison between the time period for which the shortage was declared resolved and the time period when the shortage was first declared." ECF No. 68, at 20. But nothing in the FDCA requires FDA to employ that kind of approach. The statute instructs FDA to assess, at "a period of time," whether "the demand or projected demand for [a] drug within the United States exceeds the supply of the drug." 21 U.S.C. § 356c(h)(2); *see also* 21 C.F.R. § 314.81(b)(3)(iii)(d)(1), (f). FDA chose to make that determination by considering data from [redacted]. *See* ECF No. 101, at 18 ("While the Delisting Action occasionally references narrower time frames, the decision as a whole focuses on a set of data and projected data from a specific time frame—[redacted] to [redacted]."). That decision made eminent sense, as whether a drug is in shortage is a question about the state of affairs *now*. And that turns on supply and demand in the recent past, the present, and the near future—not supply and demand from several years ago. Indeed, FDA's decision would have been reasonable even if it had considered data from a shorter period. A [redacted] the most current supply and demand numbers was more than sufficient to answer that present-day question, so FDA did not act arbitrarily or capriciously by declining to reach all the way back to 2022.

B. FDA's analysis of and reliance on Lilly's comprehensive data was both reasonable and reasonably explained.

Plaintiffs' next substantive count takes issue with FDA's analysis of the evidence Lilly supplied, which they decry as "facially incoherent and inconsistent." ECF No. 68, at 21. But Plaintiffs' nitpicking around the edges of that comprehensive analysis gets them nowhere. As the

Court explained at the preliminary injunction stage, the question "is whether the FDA's decision, that supply of the Lilly drugs outpaced demand for a period of time, was reasonable in light of the evidence before it." ECF No. 101, at 21. The answer is "affirmative." *Id.*

1. Lilly was already providing FDA with supply and demand data for both of its tirzepatide medicines when FDA decided to reevaluate the shortage determination in light of Plaintiffs' lawsuit. But to buttress its submissions, Lilly began sending FDA [redacted]. *See* Lilly App. 16-17, 27 n.60. That data included "stock reports, cumulative supply and demand reports, and distributor inventory reports," as well as additional submissions in response to FDA's requests for more detailed information. *Id.* at 17; *see also id.* at 103, 129-30, 138, 230 (FDA_000448, 000474-000475, 000483, 000575 (stock reports)); *id.* at 229 (FDA_000574 (cumulative supply and demand data)); *id.* at 118 (FDA_000463 (wholesaler inventory)); *id.* at 80-90, 114-32 (FDA_000422-000432, 000459-000477 (Lilly responses to FDA inquiries)). FDA's decision identifies each category of data and explains why it concluded that that data supports a finding that Lilly's supply of both Mounjaro® and Zepbound® is exceeding demand.

For instance, Lilly's stock reports show that Lilly consistently has "fulfill[ed] all existing orders" from wholesalers "while generally maintaining … excess inventory." *Id.* at 17. Lilly maintained anywhere from [redacted] doses of [redacted] and [redacted] doses of [redacted]. *Id.* at 18, 22; *see also id.* at 103, 129-30, 138, 230 (FDA_000448, 000474-000475, 000483, 000575) (Lilly's stock reports). And in both Lilly's [redacted]—the most relevant assessments, given that they provided the most up-to-date data at the time of FDA's determination—[redacted].

Id. at 138, 230 (FDA_000483, 000575). This [redacted] *Id.* at 17-18.

Even when there were [redacted] Lilly [redacted] *Id.* at 17. As one example, Lilly's [redacted] shows that, while [redacted]. *See id.* at 130 (FDA_000475). That [redacted], of course, [redacted]. In all events, even just looking at [redacted]. *Id.* at 103 (FDA_000448). Similarly, the [redacted]. *Id.* Particularly given that [redacted], *id.* at 24, FDA reasonably concluded that these reports [redacted] *Id.* at 18.

Lilly also provided FDA with "historic data on monthly cumulative supply and demand" over [redacted], enabling the agency to compare the volume of medicines Lilly shipped to wholesalers against "actual orders." *Id.* at 19. Data from [redacted]. *Id.* at 22, tbl. 4; *see also id.* at 229

(FDA_000574) ([redacted]).[27] And that [redacted] *Id.* at 18; *see id.* at 230 (FDA_000575) (showing Lilly had [redacted]). That data, which FDA illustrated by including [redacted], readily supports FDA's conclusion that Lilly's supply is [redacted] *Id.* at 19-22, tbls. 2-4.

Furthermore, Lilly forecasted supply and demand [redacted], showing that Lilly's projected cumulative supply would be [redacted] doses in [redacted] in [redacted], [redacted] in [redacted], and [redacted] in [redacted], while its [redacted]. *Id.* at 27; *see also id.* at 229 (FDA_000574) (forecast). Lilly modeled these projections using [redacted] *Id.* at 86, 89 (FDA_000428, 000431). And while Lilly acknowledged that [redacted]. *Id.* at 126 (FDA_000471). After reviewing Lilly's past projections, FDA found them [redacted] as [redacted]. *Id.* at 26 &

[27] Lilly also provided FDA with numerous graphs that depicted its [redacted]. *See* Lilly App. 73-74, 92-93, 100-01, 104-06, 135-36, 139-41, 227-28, 231-33 (FDA_000411-000412, 000434-000435, 000445-000446, 000449-000451, 000480-000481, 000484-000486, 000572-00573, 00576-000578).

n.57. FDA thus fairly concluded that "[redacted]" and that those predictions show that "[redacted] at least. *Id.* at 27.

Lilly also provided data about inventory in the distribution channel, including wholesaler inventory. FDA found that [redacted]," and that when [redacted] led to [redacted] *Id.* at 23; *see also id.* at 24 & tbl. 5; *see id.* at 118 (FDA_000463). Lilly also told FDA that [redacted] which showed both a [redacted] and a "[redacted]. *Id.* at 24. All of that likewise "[redacted]." *Id.* at 23.

Importantly—and in stark contrast to the one-sided picture Plaintiffs try to paint—FDA did not just blindly accept any of this data. On the contrary, FDA on numerous occasions [redacted]. *See, e.g.*, *id.* at 77-79, 108-11 (FDA_000415-000417, 000453-000456). And Lilly [redacted]. *See, e.g.*, *id.* at 80-90, 114-32, 143-47 (FDA_000422-000432, 000459-000477, 000488-000492). For instance, in an [redacted], FDA inquired about [redacted] *Id.* at 78 (FDA_000416). Lilly responded [redacted]

[redacted] *Id.* at 87 (FDA_000429). That suffices to lay to rest any claim that FDA simply accepted Lilly's submissions at face-value—let alone that FDA did not understand the data Lilly was supplying.

2. Plaintiffs next take issue with FDA's decision to consider Lilly's supply and demand data cumulatively [redacted] as opposed to looking at each month's data in isolation. But that decision was reasonable many times over.

First of all, Lilly's supply of its medicines does not reset to zero at the start of each month. With proper refrigeration, Lilly's medicines (unlike Plaintiffs', which have not been rigorously tested for stability) can be stored for up to 24 months, so Lilly's excess supply in one month carries over to the next month. As this Court correctly concluded at the preliminary injunction stage, "Plaintiffs[']insist[ence] that the FDA should have considered the data on a month-to-month basis, rather than through cumulative numbers," simply "ignores the fact that even if the charts were based on each individual month's numbers, the FDA would have had to add them together to get the total numbers for the relevant period of time." ECF No. 101, at 22-23. After all, "[i]n evaluating data for a period of time, one looks at the whole not just part." *Id.* at 23.

Once that necessary arithmetic is performed, the data plainly support FDA conclusion that Lilly's medicines are no longer in shortage, as they show that Lilly not only has been meeting demand but has been growing its excess inventory:

[redacted]

Lilly App. 19, 22. In fact, by [redacted] Lilly had [redacted]). *Id.* at 229-30 (FDA_000574-

000575). That consistent and often-growing excess inventory is proof positive that Lilly's supply of Mounjaro® and Zepbound® is exceeding demand, as it would be impossible for inventory to grow if demand were outpacing supply.

In short, Lilly provided (and continues to provide) comprehensive real-time data showing that supply consistently exceeded demand [redacted] and will continue to do so even under [redacted]. FDA's explanations for finding that data reliable, even if not perfect, were eminently reasonable.

C. FDA considered Plaintiffs' submissions and reasonably found them unreliable and/or not particularly probative.

Plaintiffs next claim that FDA did not adequately consider the information they and their allies submitted to bolster their claims of shortage. *See* ECF No. 68, at 21-22. That charge is refuted by the decision itself: FDA spent 13 pages of its 32-page memorandum addressing the various categories of information submitted purporting to show shortage and explaining in detail exactly why it did not find the information probative. *See* Lilly App. 28-41; *supra* pp.15-17. And rightly so. In stark contrast to Lilly's comprehensive hard data, Plaintiffs and their supporters offered a jumbled collection of form letters (*compare* ECF No. 110-4, at 23-24 (FDA_000828-000829), *with id.* at 30-31 (FDA_000835-000836), *and id.* at 39-40 (FDA_000844-000845)), unverified snapshots, ECF Nos. 110-7, at 9 to 110-8, at 31 (FDA_000982-001016), and results of internet polls, *e.g.*, ECF No. 110-6, at 6-9 (FDA_000970-000973), almost all addressing supply and demand (if at all) only in isolation, at the local level, and often for just a single dose, not all 12 that Lilly makes. It was therefore eminently reasonable for FDA to conclude that these submissions suffered from "important limitations" and did "not demonstrate that Lilly will be unable to meet projected demand, especially when weighed against the Lilly-provided data." Lilly App. 14.

For example, Plaintiffs and a compounder called Hims submitted results from putative surveys (really just webforms on its own websites) purportedly addressing supply issues. *See, e.g.*, ECF No. 110-6, at 6-9 (FDA_000970-000973). These "surveys" had no reliability controls to avoid fabricated or even automated submissions, did not detail what challenge the respondent faced (e.g., if a doctor refused to prescribe a drug), and did not address how long it persisted (e.g., if a prescription was filled the next day). *See* Lilly App. 218-20 (FDA_000563-000565) ([redacted]). According to the surveys' frequently asked questions page, responses were not even limited to current troubles obtaining GLP-1 products, but invited "[a]nyone who has had trouble getting access to a GLP-1 medication in the past." ECF No. 110-9, at 85 (FDA_001506). Despite all these problems, FDA considered the submissions. It just concluded that—at most—they showed only that individuals occasionally had "trouble getting prescriptions" filled, which is "most likely explained not by a continuing national shortage of supply, but by the practical dynamics of the portion of the supply chain between Lilly and the individual customers." Lilly App. 30; *see also id.* (explaining that a distributor may delay stocking a particular pharmacy "due to factors like ordering practices and incentives, cold chain logistical considerations, and retailer capacity constraints").

Plaintiffs, Hims, and a compounder advocacy group also submitted screenshots (many undated) purporting to show that certain pharmacies could not order a particular dose at a particular time from one or another wholesaler. *E.g.*, ECF Nos. 110-7, at 9 – 110-8, at 31 (FDA_000982-001016). A lawyer for "numerous pharmacies" similarly claimed that those pharmacies "'experienc[ed] significant difficulties in obtaining' tirzepatide," but those submissions did "not include information about the length of time that the product [was] … out of stock," leaving it

entirely possible that the pharmacy filled the order the very next day. Lilly App. 31 (citing ECF No. 110-2, at 25-26 (FDA_000631-000632)). Even so, FDA considered all of this evidence. It just found it *consistent* with Lilly's submissions since Lilly [redacted]. *Id.* at 32-33. FDA likewise found that anecdotal news or blog accounts did not undermine or outweigh the hard data that Lilly submitted. *Id.* at 33-34, 40. At bottom, the most that Plaintiffs and their allies succeeded in showing was that, at some unspecified points in time, some people had to wait briefly before to get a specific dose of tirzepatide from a specific retailer. But as this Court concluded at the preliminary injunction stage, "it was reasonable for the FDA to conclude that a '[redacted]' delay for a specific dose of tirzepatide on a specific retailer's website does not rise to the level of a national shortage." ECF No. 101, at 25.

FDA also reasonably explained why the production data supplied by 503B outsourcing facilities and 503A pharmacies did not support finding a shortage. "[F]or the first half of 2024"—the period covering the height of the shortage—503B pharmacies reported manufacturing only [redacted] doses compared to Lilly's [redacted]. Lilly App. 22, 36. OFA claimed that its members (503Bs) produced "[redacted] of doses" in "[redacted]," but Lilly supplied more than [redacted] that month. *Id.* And while an advocacy group claimed that four 503A pharmacies filled [redacted] prescriptions in a single month (appx. [redacted] doses), ECF No. 110-9, at 6 (FDA_001427), the total reported volume compounded paled in comparison to the [redacted] doses Lilly maintained as *excess inventory* between [redacted], Lilly App. 22, 38; *see id.* at 229 (FDA_000574). Indeed, the best Plaintiffs could muster was a news article claiming that compounded tirzepatide and compounded semaglutide—a

different drug made by a different manufacturer—*collectively* served "up to 2 million American[s]," which is *still* far less than Lilly's excess inventory. *Id.* at 37.

In short, FDA found that Plaintiffs' proffered evidence suffered from a common defect: All the screenshots, surveys, and comments suggested unavailability only at a single, isolated point in time, omitting the nature of the purported "difficulty" in obtaining Mounjaro® or Zepbound® and any context showing how long it persisted. At very best, that evidence suggested that a patient was unable to get medicine on a particular day at a particular location, which is manifestly insufficient to show that demand exceeded supply nationwide. Lilly's data, by contrast, [redacted]. *See, e.g., id.* at 17-19, 23, 24. And as this Court correctly concluded at the preliminary injunction stage, "it was not unreasonable for the FDA to give more weight to specific, reliable, comprehensive, and current information from Lilly, than news reports and blog posts from sources who may have had ulterior motives and lacked the same detailed data presented to the FDA." ECF No. 101, at 26.

Ultimately, Plaintiffs' real complaint is not that FDA failed to consider their submissions but that FDA did not find them particularly relevant or persuasive. Indeed, in their preliminary injunction briefing, Plaintiffs accused FDA of having "indulge[d]" Lilly at every turn while evincing "hyper-skepticism of all contrary evidence." ECF No. 66, at 19. In reality, FDA held all submissions to the same standard. *See* ECF No. 101, at 24 n.12. For instance, FDA declined to rely on Lilly's [redacted] Lilly

App. 25 n.44. FDA also [redacted]. *See id.* at 25 n.53. In other words, FDA held all submissions to the same standards. *See* ECF No. 101, at 24 n.12. Plaintiffs' submissions simply were not reliable enough to overcome Lilly's thorough, quantitative data. *See id.* at 26-28.

* * *

After careful consideration, FDA concluded that Lilly's "comprehensive information … regarding supply and demand" provided a "detailed quantitative picture of the supply and demand situation both over time, and at the national level, and is therefore much more probative to the analysis FDA must conduct to determine the status of the shortage." Lilly App. 31. That conclusion was not just reasonable; it was the *only* reasonable conclusion based on the information before FDA. Indeed, had FDA disregarded "detailed quantitative" and "comprehensive" data in favor of isolated screenshots and unexplained, poor-quality internet survey forms, that would have "run[] counter to the evidence before the agency." *Baylor Cnty. Hosp. Dist. v. Price*, 850 F.3d 257, 264 (5th Cir. 2017). Plaintiffs' arbitrary-and-capricious claims therefore fail as a matter of law.

III. Plaintiffs' "Contrary To Law" Claim Fails.

Plaintiffs' final claim accuses FDA of adopting an "overly restrictive definition" of "shortage." ECF No. 68, at 22-23. In Plaintiffs' view, a "shortage" exists anytime there is a "[d]elay in shipping of [a] drug," no matter how minor. *Id.* (quoting 21 U.S.C. § 356e(b)(3)(F)); *see also* ECF No. 66, at 20 (arguing that FDA should deem a drug to be in shortage anytime some "patients cannot get the product," at some place in the United States (however isolated), at any given moment (however temporary)). Plaintiffs' myopic construction distorts the statute and defies common sense.

Starting with the text, *see generally Van Loon v. Dep't of the Treas.*, 122 F.4th 549, 563 (5th Cir. 2024), Section 356e(a) of the FDCA requires FDA to "maintain an up-to-date list of drugs that are determined by [FDA] to be in shortage in the United States." 21 U.S.C. § 356e(a). Section 356e(a) does not define the term "shortage," but a neighboring section does: Section 356c defines "shortage" or "drug shortage" as "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug." *Id.* § 356c(h)(2). FDA has interpreted the term "shortage" in § 356e the same way. *See* Lilly App. 2; 21 C.F.R. § 314.81(b)(3)(iii)(d)(1), (f). And rightly so. Courts typically presume "that the same term has the same meaning when it occurs here and there in a single statute," *Env't Def. v. Duke Energy Corp.*, 549 U.S. 561, 574 (2007), and nothing in the FDCA suggests that Congress meant to jettison that principle here. Nor is there any logical reason why the term "shortage" would carry a different meaning in § 356e(a), as the supply-and-demand focused definition provided in § 356c(h)(2) comports with the ordinary understanding of the term. "The standard textbook definition of a shortage is an excess of quantity demanded over quantity supplied at the prevailing price." David Kaserman, *Markets for Organs: Myths and Misconceptions*, 18 J. Contemp. Health L. & Pol'y 567, 570 (2002) (citing Robert B. Ekelund, Jr. & Robert D. Tollision, *Microeconomics: Private Markets and Public Choice* 67 (6th ed. 2000)); *see also, e.g.*, *Shortage*, Black's Law Dictionary ("A situation in which there is not enough of something that people want or need").

Plaintiffs insist that § 356c(h)(2) cannot inform the meaning of "shortage" in § 356e because § 356c(h)(2) provides its definitions "[f]or purposes of [that] section." ECF No. 68, at 22-23. But the "normal rule" that "'identical words used in different parts of the same act are intended to have the same meaning'" is "*strengthen*[*ed*]," not undermined, when there is an "explicit definition" of the term "in the same subchapter," even if it is not in the same section.

Sorenson v. Sec'y of Treas., 475 U.S. 851, 860 (1986) (emphasis added) (quoting *Helvering v. Stockholms Enskilda Bank*, 293 U.S. 84, 87 (1934)). Sections 356c and 356e are not just "in the same subchapter" of the FDCA (Subchapter V); they are two sections away in the same Part (Part A) and were enacted simultaneously in the same bill. *See* Pub. L. No. 112-144, §§ 1001, 1004, 126 Stat. 993, 1100, 1104-05 (July 9, 2012). Moreover, while the general presumption that the same term carries the same meaning throughout a statute is "not [a] rigid" rule, it yields only when the statute itself indicates that Congress used the words "in different parts of the act with different intent." *Env't Def.*, 549 U.S. at 574. And nothing in the relevant provisions suggests that Congress intended "shortage" to mean something different in § 356e than in § 356c(h)(2). To the contrary, § 356e focuses on the same supply-and-demand concepts as § 356c(h)(2). For example, § 356e requires the Secretary to identify "[t]he reason for the shortage," "selecting from … categories" set forth by Congress. 21 U.S.C. § 356e(b)(3). Those categories focus on supply and demand, asking, e.g., if there is a "[s]hortage of an active ingredient" or "inactive ingredient component," or a "[d]emand increase." *Id.* § 356e(b)(3)(C)-(D), (G).

Plaintiffs fixate on one item on that list—"Delay in shipping of the drug"—and from that, try to infer that a shortage exists whenever any such delay exists. *See* ECF No. 68, at 22. But a drug is not in a nationwide shortage just because there has been some delay somewhere in shipping it. After all, if there is more than enough of a drug to go around, then it is not in shortage just because someone who needs it happens to run into a problem trying to acquire it. Plaintiffs' contrary argument rests on a classic logical fallacy. The fact that A (shipping delays) *can* cause B (a shortage) does not in any way suggest that B *always* exists whenever A does. Take, for instance, another entry on the list: "Regulatory delay." Delays at FDA do occur, and Congress has passed

at least seven statutes addressing the problem.[28] But no one would contend that a drug is in shortage every time any regulatory delay occurs. Rather, one must evaluate the *impact* of the regulatory delay to see *whether* it caused a shortage—that is, whether the delay caused the available drug supply to be insufficient to meet nationwide demand.

Making matters worse, Plaintiffs' argument ignores the point of the drug shortage list—i.e., determining when emergency measures are warranted. Every shortage must be reported to Congress, and its existence has significant and immediate consequences. 21 U.S.C. § 356c-1. A shortage obligates FDA to expedite inspections and the adjudication of applications. *See id.* § 356c(g). It can restrain FDA's enforcement authority. *See id.* § 356d(c). It opens a new pathway for manufacturers to distribute investigational versions of the drug. *See* 21 C.F.R. § 312.315(a)(3)(ii). It grants hospitals the ability to repackage the drug while it is in short supply. *See* 21 U.S.C. § 356f. And it authorizes outsourcing facilities to use the drug substance in their compounding activities. *See id.* § 353b(a)(2)(A)(ii). By Plaintiffs' telling, all of these extraordinary measures would be triggered any time some patient experienced a delay in obtaining a prescribed drug, no matter how brief or isolated. Indeed, if Plaintiffs are right, then a medicine could find itself on the shortage list for something as trivial as a delay owing to a flat tire on a shipping truck that will be remedied within a day. That would make the shortage list useless as a tool for what it is designed to accomplish—namely, identifying when extraordinary measures are warranted. It would also create a regime that is completely unworkable for FDA, which would have to continuously monitor every pharmacy in the country (and perhaps even every shipment of

[28] *See, e.g.*, Animal Drug User Fee Act, Animal Generic Drug User Fee Act, Biosimilar User Fee Act, Generic Drug User Fee Act, Medical Device User Fee Act, Over-the-Counter Monograph Drug User Fee Act.

every FDA-approved drug) and add or remove drugs from the list on a near-constant basis, just to uphold its statutory mandate to keep an "up-to-date list." *Id.* § 356e(a).

The far more sensible understanding of shortage is the one set forth in § 356c(h)(2): "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug." That definition focuses on the kind of events that create a meaningful delta between supply and demand nationwide, not any conceivable impediment to acquiring a drug in a particular locale. That is evident from various other provisions in § 356c. For instance, § 356c(a) requires manufacturers of certain "life-supporting" or "life-sustaining" drugs to "notify" FDA of, *inter alia*, "a *permanent discontinuance* … or an *interruption* of the manufacture of [such a] drug that is likely to lead to a *meaningful disruption* in the supply of that drug in the United States." *Id.* § 356c(a) (emphases added). And § 356c(h)(3) defines "meaningful disruption" to "(A) mean[] a change in production that is reasonably likely to lead to a reduction in the supply of a drug by a manufacturer that is more than negligible and affects the ability of the manufacturer to fill orders or meet expected demand for its product; and (B) … not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time." *Id.* § 356c(h)(3). Section 356c(c) in turn requires FDA to "distribute … information on the *discontinuance* or *interruption* … to appropriate organizations" and to do so "as described in section 356e of this title." *Id.* § 356c(c) (emphases added). And § 356c(g) requires FDA to expedite certain reviews and inspections *if* the agency determines that a "meaningful disruption" will lead to "a drug shortage of a drug described in subsection (a)." *Id.* § 356c(a), (g).

As all of those provisions reflect, Congress was focused on the kinds of interruptions or changes that will actually cause demand to exceed supply on a national level for an appreciable

period of time, not any and all things that might impede someone's ability to acquire a particular drug in a particular place at a particular time. So too in § 356e. Congress plainly intended these provisions to work in tandem—indeed, it enacted them together—as each creates a mechanism whereby FDA will be informed if a drug is in shortage, so it can take steps to address that shortage to the extent necessary. That makes sense if a shortage is understood as a situation where demand is exceeding supply on a nationwide level, as the kind of steps that both § 356ce and § 356e contemplate and trigger are focused on increasing supply. But it makes little sense if the concept of a shortage is expanded to cover any situation where there is any kind of disruption in obtaining or shipping a medication, as the statute does not focus on removing any and all potential impediments to access, no matter how isolated and/or fleeting. By interpreting "shortage" consistently across the provisions, FDA's reading ensures that the sections work in harmony towards the common goals of mitigating nationwide shortages and ensuring patient access to safe and effective medicines. *See Wyeth v. Levine*, 555 U.S. 555, 566 (2009); *cf. Lawson v. FMR LLC*, 571 U.S. 429, 459 (2014) ("The provisions' parallel text and purposes counsel in favor of interpreting the two provisions consistently.").

In short, FDA's long-standing interpretation of "shortage" as focusing on supply and demand nationwide comports with text, context, and common sense, while Plaintiffs' proposed interpretation would lead to absurd results that do nothing to further the objectives of the shortage list. Plaintiffs' fifth claim accordingly fails as a matter of law too.

CONCLUSION

For all these reasons, the Court should grant Lilly's motion for summary judgment on all of Plaintiffs' claims.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on April 2, 2025, a copy of this document was served electronically in accordance with the Federal Rules of Civil Procedure.

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